

REMARKS

Upon entry of the following amendments, claims 163-168, 170-171, 173-180, 182-188, 190-198, and 200-202 constitute the pending claims in the present application. Claims 1-162, 169, 172, 181, 189, and 199 are cancelled.

Amendments

Applicants have amended claim 163 for clarity. Applicants have cancelled claim 169 without prejudice.

Applicants have amended claims 175, 185, 193 to incorporate the subject matter of claims 181, 189, and 199, respectively, and have cancelled claims 181, 189, and 199. Applicants have also amended claims 182, 190, and 200 to correct antecedence.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the outstanding Office Action using the enumeration from the Action.

1. Information Disclosure Statement

The Office maintains that the Information Disclosure Statement dated September 20, 2004 ("the IDS") fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document, each non-patent literature publication or that portion which caused it to be listed. Applicants disagree and respectfully direct the Office's attention to 37 CFR 1.98(d). Applicant is not required to supply the Office with copies of references which have been previously submitted to the Office in an earlier application if "[t]he earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. 120..." (37 CFR 1.98(d)(1)). Applicants assert that these criteria have been met and direct the Office's attention to page 1, paragraph 3 of the IDS where it is stated:

A copy of each reference on the PTO/SB/08 is not supplied because the references were previously cited by or submitted to the Office in a prior application number 10/015114, filed November 12, 2001, now Patent No. 6,752,814 and prior application number 09/023965, filed February 13, 1998, now Patent No. 6,423,080 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

Hence, the IDS properly identified the earlier applications where the art had been previously submitted to the Office, and the earlier applications are relied on in the present application for an earlier effective filing date under 35 U.S.C. 120. Accordingly, the IDS is compliant with 37 CFR 1.98, and Applicants respectfully request that the IDS be entered and the information contained therein considered.

3-5. Claim Rejections – 35 U.S.C. 102 Over U.S. 5,336,231 to Adair

Claims 175-181 and 185-189 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,336,231 to Adair (“Adair”). Applicants traverse the rejection to the extent that it is maintained over the claims as presently amended.

The Office alleges that Adair teaches a system capable of treating urinary incontinence. Applicants disagree and respectfully highlight that there is no teaching or suggestion in Adair that the devices presented therein are capable of treating urinary incontinence. Adair teaches devices for ligation of large vessels attached to a body part by fibrous tissue (see Abstract). Applicants assert that ligation of large vessels is not synonymous with treating urinary incontinence, for example, by providing a urethral platform with a sling assembly described in the present application.

Moreover, Adair further does not teach “a sling assembly comprising a supportive sling...” as presently recited in claims 175 and 185. Although the Office contends that element 82 in Fig. 28-37 of Adair is a sling, Applicants point out that element 82 is a portion of suture 18 (see column 8, lines 6-8); it is not a supportive sling for treating urinary incontinence. One of skill in the art would recognize that a suture, being a thin thread or wire, does not have the ability to provide a urethral platform to support peri-urethral tissue as does a supportive sling. Consequently, the suture portion 82 of Adair is not equivalent to or interchangeable with the supportive sling of claims 175 and 185, and Adair does not teach or suggest all the elements of claims 175 and 185.

Since a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (see MPEP 2131 quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)), Adair cannot be said to anticipate claims 175 and 185 or claims dependent thereon. As such, Applicants request reconsideration and withdrawal of the anticipation rejection over Adair.

6-7. Claim Rejections – 35 U.S.C. 102 Over U.S. 4,935,027 to Yoon

Claims 193-199 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 4,935,027 to Yoon (“Yoon”). Applicants traverse the rejection to the extent that it is maintained over the claims a presently amended.

The Office alleges that Yoon teaches a system capable of treating urinary incontinence. Applicants disagree and respectfully highlight that as is the case with Adair, in Yoon there is no teaching or suggestion that the devices presented therein are capable of treating urinary incontinence. Yoon teaches devices for suturing of tissue from a position remote from the suture site (see Abstract). Applicants assert that suturing of tissues is not synonymous with treating urinary incontinence, for example, by providing a urethral platform with a sling assembly described in the present application.

Furthermore, Yoon does not teach “a sling assembly comprising a supportive sling...” as presently recited in claim 193. The Office contends that Yoon teaches a sling and refers to column 2, lines 9-11 of Yoon, which states “The suture material can be any of a variety of rigid, semi-rigid, bioabsorbable or non-bioabsorbable *suture material*.” (emphasis added). Applicants assert that the skilled artisan would take this passage of Yoon at face value, *i.e.*, that the suture material of Yoon can be made of any *suture material* that is rigid, semi-rigid, bioabsorbable or non-bioabsorbable. This passage does not teach or suggest that the suture material of Yoon can be a supportive sling for treating urinary incontinence, and the remaining disclosure of Yoon similarly fails to teach or suggest the claimed subject matter. As noted above, Applicants assert that one of skill in the art would recognize that a suture, being a thin thread or wire, does not have the ability to provide a urethral platform to support peri-urethral tissue as does a supportive sling. Consequently, the suture material of Yoon is not equivalent to or interchangeable with the supportive sling of claim 193, and Yoon does not teach or suggest all the elements of claim 193. Accordingly, Yoon cannot be said to anticipate claim 193 or claims dependent thereon, and Applicants request reconsideration and withdrawal of the anticipation rejection over Yoon.

7-11. Claim Rejections – 35 U.S.C. 103 Over Adair In View of U.S. 3,580,256

Claims 182-184 and 190-192 are rejected under 35 U.S.C. 103(a) as being obvious over Adair as applied to claims 175 and 185, in view of U.S. 3,580,256 to Wilkinson et al. (“Wilkinson”). Applicants traverse the rejection to the extent that it is maintained over the claims as currently amended.

As noted above, Adair fails to teach all the elements of claims 175 and 185, for example, the supportive sling. Wilkinson teaches a pre-tied suture for suturing (see Abstract); the reference does not teach or suggest a supportive sling for treating urinary incontinence. As noted above, a suture is quite different from a sling.

Pursuant to MPEP 2142, “[t]o establish a prima facie case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since Adair and Wilkinson, either alone or in combination, fail to teach all the features of claims 175 and 185, these claims and those dependent thereon cannot be found obvious over these references. As such, Applicants request reconsideration and withdrawal of the obviousness rejection of claims 182-184 and 190-192 which are dependent on claims 175 and 185, respectively.

12-18. Claim Rejections – 35 U.S.C. 103 Over Yoon In View of Wilkinson

Claims 163-171, 173-174, and 200-202 are rejected under 35 U.S.C. 103(a) as being obvious over Yoon in view of Wilkinson. Applicants traverse the rejection to the extent that it is maintained over the claims as currently amended.

As noted above, neither Yoon nor Wilkinson, alone or in combination, teaches or suggests all the features of claims 163 or 193, for example, a supportive sling. Hence, claim 163 and those dependent thereon and claims 200-202, which are dependent on claim 193, are not obvious over Yoon in view of Wilkinson.

Furthermore, the Office acknowledges that the use of a pouch over any portion of the sling assembly is not taught by Yoon. Yet the Office contends without providing evidence or any other supportive rationale that it would have been obvious to one of ordinary skill in the art to combine

the sheath of Wilkinson with the alleged sling assembly of Yoon “because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.” Applicants disagree.

In establishing a *prima facie* case of obviousness, MPEP 2142 states:

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Applicants contend that the Office has not met the above burden and note that neither Yoon nor Wilkinson teaches the desirability of combining their teachings in the manner suggested by the Office. Neither reference teaches that the body needs protection from sutures provided therein, and neither reference teaches or suggests that the sheath of Wilkinson is capable of accomplishing such protection. The Office’s unsupported assertion, possibly based on Applicants’ own disclosure, that pouches were commonly used to protect the body, cannot provide the missing motivation when not grounded in the art of record. Thus, the motivation requirement for establishing a *prima facie* case of obviousness has not been met.

Moreover, the Office is silent with regard to the requirement that the suggested modification of the Yoon suture with the Wilkinson sheath have a reasonable expectation of success. *See* MPEP 2142 and *In re Vaack supra*. Applicants assert that placing the sheath of Wilkinson over the suture of Yoon would not succeed - when the “frangible” sheath of Wilkinson (see column 2, lines 1-5) is run through the torturous path created by the numerous pulleys and channels of the Yoon device, the sheath will, according to its intended function, likely tear and clog the device and/or be rendered incapable of further “protection” of the suture. Accordingly, no evidence has been offered by the Office to fulfill the expectation of success requirement for establishing a *prima facie* case of obviousness, and so this requirement has also not been met.

As noted above, the Office has provided no explanation or support to satisfy the motivation or expectation of success requirements for an obviousness the rejection. Applicants respectfully

remind the Office that the Federal Circuit has articulated a standard whereby the Office must establish a rational connection between the its fact-findings and its ultimate action. *Dickinson v. Zurko*, 119 S.Ct. 1816 (1999). In light of Applicants' arguments and the presumption in favor of Applicants, it is respectfully asserted that the necessary elements of the instant obviousness rejection are not supported by any evidence of record, let alone the high standard of substantial evidence dictated by *Dickinson*. As such, the rejection fails to rise above the "arbitrary, capricious" standard applied under the "substantial evidence" test of the Administrative Procedure Act (5 U.S.C. § 706(2)(E)) and is therefore improper.

Hence, for the reasons above, Applicants assert that none of the three requisite criteria for establishing a *prima facie* case of obviousness have been met. Applicants request reconsideration and withdrawal of the obviousness rejection over Yoon in view of Wilkinson.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P03-006 from which the undersigned is authorized to draw.

Dated: February 13, 2007

Respectfully submitted,

By 

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